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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,598	04/26/2001	H. Robert Horvitz	01997/525002	8753

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EXAMINER

PURI, BEENA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,598

Applicant(s)

HORVITZ ET AL.

Examiner

Beena Puri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim(s) 1-11, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims are drawn to a method for determining the activity range of a test compound, by contacting a first nematode expressing a mutated CeSERT polypeptide with reduced capacity to take up serotonin relative to wild-type and assaying a defined behavior of first nematode and further comparing defined behavior of first nematode to a second nematode not contacted with said compound.

The invention is directed to determine the activity range of a test compound against wild type nematode and three defective mutant nematodes expressing a mutated CeSERT polypeptide. Three mutants disclosed by applicant are (1) mod-5 CeSERT (n822) polypeptide with T-to-A transversion mutation resulting in a C225opal

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nonsense substitution, (2) mod-5(n823) polypeptide with C-to T transition mutation resulting in a P569S mis-sense substitution (3) mod-5(n3314) null allele polypeptide containing a 1688 base pair deletion in mod-5 genomic locus.

The specification teaches the phenotypic characterization of well fed and food deprived three mutant nematodes listed above and shows hyper enhanced slowing response for said mutants compared with wild type animal (Fig.2). In the working examples for testing the compounds; the specification teaches genetic interactions and serotonin- and MOD-5 CeSERT-dependence of potentiating effect of fluoxetine and show enhanced slowing response by locomotion assay, egg laying behavior, nose contraction or defection (Fig. 5 a, b, & c) under food deprived and food-deprived on fluoxetine conditions for several different mutants. It is noted from the specifications that applicant has tested several different mutant animals in the working experimentations. The working examples include one single mutant mod-5 CeSERT(n3314) from three mutants listed above. Claim 6 is drawn to three mutants mod-5 CeSERT (n3314), mod-5 CeSERT (n822), and mod-5 CeSERT (n823). There is no indication in the specification that could provide evidence to the artisan that two other mutants are also used to test the activity range of a compound. A mutant mod5 (n3314) is tested along with other mutants in locomotion assay and behavior of the mutant is shown in relation to egg laying, nose contraction and defection against a test compound. However, the specification does not teach about the behavior of two other mutants in relation to a test compound. In the working experimentation, an activity range of the test compound is correlated to the change in behavior of a nematode at a particular concentration that will

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vary from one mutant animal to other mutant animal. Each mutant will show different behavior against the testing compound at a particular concentration. Also the specification does not provide any evidence of testing the compound for a mutant animal in the presence of second animal and studying the defined behavior of first animal against second animal. A test compound at a particular concentration will have different effect on first nematode behavior when tested in the presence of second nematode because second nematode may interfere on the effect of a particular concentration of a test compound against first nematode.

In conclusion, the claims would require an undue amount of experimentation without such guidance in the specification and the lack of correlative working examples, without a predictable degree of success on part of the skilled artisan.

2. ***Drawings***

The drawing have been reviewed and are objected under 37 CFR 1.84 or 1.152. See attached Notice of Draftsperson's Patent Drawing Review.

3. ***Oath/Declaration***

Oath/Declaration does not provide the signature for one of the inventors.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Beena Puri, Ph. D. whose telephone number is (703) 306-0284. The examiner can normally be reached on 8:00 a.m. EST to 4:30 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Debroah Clark can be reached on (703) 305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630

Beena Puri, Ph.D.
Patent Examiner
AU 1633

bp
Oct. 17, 2001